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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,663	PRASCH ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' amendment and declaration, which were filed on 5 April 2007.
- The 35 USC 112, 2nd paragraph rejections are withdrawn in view of the amendment.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 18-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 18-34 are drawn to a "depot" medicament formulation. According to the instant specification, "[r]elease of the active ingredient is intended with the described drug forms to take place in a delayed and gradual manner, resulting in a prolonged action for these drug forms in the sense of a depot." *See* page 1, lines 9-12. However, no evidence is provided in the specification that applicants have accomplished "depot" pharmacokinetics. No examples or data are provided that show a delayed or prolonged release of active agent using the medicament formulation claimed.

2. Claims 18-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, claims 18-34 are drawn to a "depot" medicament formulation. While examiner acknowledges that the term "depot" is given a broad definition in the instant specification (*see* page 1, lines 10-12), the term is not defined by the instant specification in a clear and concise manner as applied to the invention being claimed. As such, the disclosure of the instant specification is not sufficient to support the concept of "depot" medicament formulation, as claimed, and requires further clarification.

3. Claims 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the specification does not teach how to make a medicament formulation comprising ceramic granules or calcium phosphate. No examples are provided.

4. Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the specification does not teach how to make a bone replacement implant. No examples are provided.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-25 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heath, et. al. (WO 97/44015).

Heath, et. al. teach a granulated fibrin tissue adhesive formulation (*see* col. 3, lines 28-39). The disclosed formulation is comprised of:

- the blood plasma protein of instant claim 18 (*see* page 2, line 35);
- the thrombin of instant claim 18 (*see* page 2, line 35);
- the carrier granules of instant claim 18 (*see* page 3, lines 9-18);
- the active agent of instant claim 18 (*see* page 2, line 35);
- the carrier system of instant claims 19-21 (*see* page 3, lines 9-18);
- the granule comprised of an internal core of mannitol and external layer plasma protein of instant claims 22 and 23 (*see* page 3, lines 32-36);
- the substance which promotes wound healing of instant claim 28 (*see* page 2, line 35);
- the topical, parenteral, and transdermal routes of administration of instant claims 29-31 (see Example); and
- the process of producing a depot medicament of instant claim 34 (*see* page 3, lines 19-25).

Heath, et. al. explain that a granulated blood plasma protein medicament formulation formed by spray-drying is beneficial because it provides, "...good flow

properties, enhanced, effective delivery to the active site, and dissolution only at the site, not in the delivery system." *See* page 3, lines 1-7.

While Heath, et. al. do not explicitly teach the particle sizes recited in instant claims 18, 24, and 25, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable particle sizes through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in particle size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant particle sizes.

Although the Heath, et. al. reference does not disclose the fluidized bed drying step of instant claim 18, the process of fluidized bed drying recited in claim 18 is not essential to a determination of patentability of the formulation disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a granulated blood plasma protein medicament formulation, as taught by Heath, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a formulation because of good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, as explained by Heath, et. al.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-25, 28-31 and 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 13 of U.S. Patent No. 6,596,318 (U.S. '318). Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. '318 claims a granulated blood plasma protein medicament formulation (*see* claim 1) produced by fluidized bed drying (*see* col. 16).

One of ordinary skill in the art at the time of the invention would have expected similar effects from the formulation of the instant claims, given the claims of U.S. '318. Thus, the instant claims for a granulated blood plasma protein medicament formulation would have been obvious given the claims of U.S. '318.

* * * * *

Response to Arguments

Applicant's arguments filed on 5 April 2007 have been fully considered but they are not persuasive.

35 USC 112, 1st Paragraph

Enablement

1. Applicants argue that the examiner has not provided a reasonable basis for the determination that the claimed composition will not work as a depot. *See* remarks, page 6, second paragraph.

Examiner respectfully submits that the basis for the enablement rejection, as made clear in the previous Office action, is that applicants provide no evidence in the specification that the claimed composition will work as a "depot" formulation.

2. Applicants argue that the specification need not contain specific examples. *See* remarks, page 6, third paragraph.

Whether the specification contains examples or not, the specification must provide some evidence that the claimed composition will work as a "depot" formulation. Examiner respectfully submits that no evidence that the claimed composition will work as a "depot" formulation was provided in the specification.

3. Applicants argue that the instant specification is enabled because it, "...(i) provides several examples of such claimed compositions...(ii) defines the term "depot"...(iii) provides several examples of depot formulations from the prior art... and (iv) discloses various modes for administration of the claimed compositions..." *See* remarks, page 7, second paragraph.

Examiner respectfully submits that the points recited above reaffirm examiner's contention that the specification is not enabled for a "depot" formulation. Examiner notes that none of the points recited above provide evidence that applicants' claimed composition worked as a "depot" formulation.

*

Written Description

1. Applicants argue that, "...the meaning of the term 'depot formulation' as provided in the present application is well established in the art and is widely used to refer to formulations being in storage and/or acting over a prolonged period of time." *See* page 8, first paragraph.

Examiner respectfully notes that the phrase "depot formulation," as recited in applicants' remarks, is not used in the instant specification. Rather, the phrase used in the instant specification is "depot medicament formulation."

At page 1, lines 10-12 of the instant specification, applicants describe the subject matter of the instant specification using the phrase "in the sense of a depot." Applicants qualify the subject "depot" with the noun "sense." However, applicants claim a "depot medicament formulation" without any qualification.

The phrase "depot medicament formulation" is not defined anywhere in the specification. Moreover, the term "depot" – without a qualifying noun – is not defined anywhere in the specification.

Examiner respectfully submits that this fundamental disconnect between the description and the claims renders the disclosure of the instant specification insufficient to support the concept of a "depot medicament formulation," as claimed.

2. Applicants argue that, "...the definition provided at p. 1, ll. 9-12 of the present application is further clarified at p. 4, ll. 27-5, which states that the depot drug forms "achieve a delayed or extended release of active ingredient with a slow, constant uptake of active ingredient into the blood stream and thus a constant concentration level of active ingredient in the blood." *See* page 8, first paragraph.

Examiner respectfully submits that the excerpt above describes a combination of a fibrin glue with therapeutically active substances, not a "biodegradable depot medicament formulation." Furthermore, applicants do not define a "biodegradable

depot medicament formulation" to be a combination of a fibrin glue with therapeutically active substances.

3. Applicants direct the record to page 16, line 33 – page 17, line 10 of the instant specification to show a description of how to make a medicament formulation comprising ceramic granules or calcium phosphate as well as how to make a bone replacement implant. *See* page 8, third paragraph.

Examiner respectfully submits that the cited passage merely provides a broad outline of what the granules are comprised of and basic coating and compression steps. The disclosure is not sufficient for a person of ordinary skill in the art to practice the invention.

The attempt to incorporate subject matter into this application by reference to DE 198 49 589 C1 is ineffective because applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

*

35 USC 103

Applicants argue that the instant application is distinguished from the prior art by the method of drying. *See* remarks, pages 10-11.

The process of fluidized bed drying recited in claim 18 is not essential to a determination of patentability of the formulation disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Double Patenting

1. Applicants argue that the instant application is distinguished from the '318 patent because the former discloses a medicament formulation while the later discloses a sealant. *See* remarks, page 11, last paragraph.

Examiner respectfully submits that both a medicament formulation and a sealant are intended uses of the composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

2. Applicants argue that the instant application is distinguished from the '318 patent because the former discloses a formulation comprising a biodegradable blood plasma

protein and an active ingredient while the later discloses a mixture of blood plasma proteins. *See* remarks, page 12, last paragraph.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."). *See* MPEP 2111.03. Examiner respectfully submits that the claims of the '318 patent recite the transitional phrase "containing." Thus, the scope of the '318 claims is broad enough to encompass a biodegradable blood plasma protein and an active ingredient.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HUMERA N SHEIKH
PRIMARY EXAMINER

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